Hogan Lovells

State Medical Device Distribution & Manufacturer Licensing

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Medical device manufacturers who distribute prescription and over-the-counter (OTC) devices are subject to complex state licensing requirements that can attach to their manufacturing and/or distribution activity. Further, many medical device manufacturers partner with third-party logistics (3PL) providers that are also subject to separate state licensing requirements; all of which are separate from the business licenses that companies need to obtain to conduct business in the state.

Licensing rules vary between prescription and OTC devices, recipient, and location. There are even a fair number of states that have no licensure requirements for medical devices of any sort. Adding further complexity, most state licensing regimes are developed to handle prescription drugs and controlled substances and are not always suitable for the distribution models used for medical devices and are not always applied to medical devices.

Where medical device companies are required to hold state licenses, companies must complete complex initial licensing and renewal forms with variable requirements and guidelines.

Contacts

Jodi Scott,
Denver

Wil Henderson,
Denver

Practices

Medical Device and Technology Regulatory

Additionally, many licenses come with associated process requirements that must be woven throughout the distribution processes that are often part of the company's Quality Management System (QMS).

Our knowledge of manufacturer Quality System requirements and industry experience in the distribution of medical devices, gives us the type of background and experience to help you navigate this complex and varied area of compliance.

Representative experience

Assisted client in addressing state licensing for new product launches by identifying those states that required licensure and assisting the company in preparing those applications.

Negotiated enforcement discretion with states for medical devices where licenses may have been required under the letter of the law, but the states elected not to require licensure due to the low risk of the product and low benefit of licensure.

Assisted companies with developing remediation strategies and handling notices of violations from state regulatory bodies.

Assisted in the negotiation of distribution agreements with client distribution partners and 3PLs to ensure that state licensing obligations were met.

Latest thinking and events

News

"Remanufacturing" or "Servicing"? New FDA guidance clarifies distinction for medical devices

News

The European Commission issues guidance concerning management of legacy devices in EUDAMED

News

Biden Issues wide-ranging Buy American Executive Order – FAR rulemaking to come

News

Comment period ending for proposal to automatically sunset

HHS/FDA/CMS regulations

Insights

UK regulation of medical devices from 1 January 2021

News

COVID-19 Report for Life Sciences and Health Care Companies
(21 - 24 September 2020)